

Original Article

An Analysis of the Efficacy of *Sepia officinalis* in the Management of Distress during Climacteric Years

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ABSTRACT

Background- Climacteric is the phase in the ageing of women marking the transition from the reproductive phase to the non reproductive state. According to a survey, 44% of post menopausal women used hormonal replacement therapy (HRT). Aim: The present analysis is of the cases prescribed with *Sepia officinalis* to evaluate its efficacy in DDCY. Method- An open prospective observational study was undertaken by a research institute at six centers for a period of 4 years (including a follow up period of 1 year) as per the protocol. The cases where Sepia (n=53) was found indicated and prescribed were taken up for analysis. The data was analyzed statistically by using the “Wilcoxon sign rank test” on SPSS for the symptoms score and gynecological findings and “t test” for laboratory findings. Results- The mean symptom score at the base line was 13.68 (4.27) and at the end of treatment was 2.81 (2.63), which is statistically significant ($P<0.05$). Out of 53 patients who completed their follow up, 37 patients showed marked improvement, 14 patients showed moderate improvement and 2 patients showed mild improvement. Forty (40) patients were investigated for FSH both at entry and completion, the FSH value reduced in 24 cases. Out of 15 patients who were investigated for lipid profile on completion of the study, the level of lipid cholesterol and Triglycerides (TG) were reduced in 6 patients, HDL was increased in 12 patients which is statistically significant ($P=0.024$), LDL was decreased in 8 cases and VLDL was decreased in 7 cases. Conclusion-Results of the analysis showed the usefulness of Sepia in management of distress during climacteric years. Further RCT are being conducted to validate the effectiveness of Sepia in DDCY.

Key words: *Sepia officinalis*, Distress during Climacteric Years, Cuttlefish

S*epia officinalis* is an animal remedy made from the ink of the cuttlefish [1]. The cuttle-fish inhabits the seas of Europe, especially the Mediterranean. Sepia in a dry state appears to be a dark blackish-brown, solid mass, of shining, very brittle fracture, having a faint smell of seafish. The cuttle-fish is without an external shell, one to two feet long, soft-gelatinous, of a brown color verging on red, and spotted black [2]. *Sepia officinalis* is one of the most important woman's remedy in homoeopathy used for gynecological disorder [1]. Within world of homoeopathy, *Sepia officinalis* has been recognized as one of the 20 remedies that have widest range of application. In 1834, *Sepia officinalis* was discovered as potential homoeopathic remedy. Sepia can work on issues related to uterus, vagina,

and ovaries. It may work for symptoms of hot flushes experienced during menopause [3].

Climacteric period in the aging woman is the transition from the reproductive phase to non reproductive state. In this period, woman of age around 40-55 years presents the symptoms like hot flushes, night sweat and mood swings, dysuria, pruritus vulva. These are the symptoms which are felt by the menopausal woman. Homoeopathic literature reveals that *Sepia officinalis* is a very good medicine for Distress During Climacteric Years (DDCY), if prescribed on the totality of symptoms of patients. The homeopathic remedy *Sepia officinalis* is prepared from unadulterated pigments of the ink enclosed in the cuttlefish's ink sac. The pure brownish-grey ink obtained from the cuttlefish's

ink sac forms the basis of this medication. Soon after the ink is obtained from the cuttlefish, it is dehydrated and succussed. Subsequently, the dried ink is profusely diluted till the desired levels are attained by adding huge amounts of milk sugar (lactose). The resultant solution is the homeopathic remedy *sepia*, which does not retain any trace of ink and is safe for human use [4]. The pure, powdered *sepia* is covered with five parts by weight of dilute alcohol, poured into a well-stopper bottle, and allowed to remain eight days in a dark, cool place, being shaken twice a day. The tincture is then poured off, strained and filtered. 3 Hahnemann, with five others, first proved *Sepia*, and it was reproved by the American Institute [5]. The present analysis is of the cases prescribed with *Sepia officinalis* to evaluate its efficacy in DDCY.

METHODS

The study was conducted as an open observational study by a tertiary care institute at six centers (including a follow up period of 1 year). Clearance by the ethical committee was obtained before initiation of the study. The study was verbally explained to each patient with the help of patient information sheet printed in regional language and thereafter a written informed consent was obtained from the patients. Female patients between the ages of 40 and 55 years and with changes in menstrual pattern or with cessation of menstruation for at least 1 year were screened from the general outpatient department of the institutes/units. The inclusion criteria were female with cessation of menstruation for at least 1 year with FSH level >40 mIU/ml or women in the perimenopausal period with serum FSH ranging between 10 and 40 mIU/mL on the second day of menstrual cycle. The patients who had an artificial menopause and were on HRT, had a history of breast or reproductive organ cancer, uncontrolled HTN, DM, Chronic Renal failure and severe psychiatric disturbance based on history, relevant investigation or physical examination, were excluded.

As the study was done at six centers, a uniform questionnaire Distress during climacteric years symptoms scale (DDCYSS) was devised by the council to remove the bias of the investigator for assessing the individual symptoms. The cases which were prescribed with *Sepia officinalis* were taken from the above study and analyzed. It was found that *Sepia* was one of the most effective medicines in the management of DDCY. At entry, an objective assessment of 15 predefined symptoms menopause was done on DDCYSS. Each symptom in DDCYSS was quantified considering its frequency, duration and intensity by attributing scores 0-4. Also every patient was subjected to per vaginal examination as required at the base line. After the first visit, follow up was done every week for a month, then every 2 weeks for 3 months and then monthly for 8 months. Evaluation of symptoms was done as per DDCYSS at every follow up and per vaginal examination was done at the 3rd, 6th, 9th,

and 12th month. The patients were followed up for a period of 1 year.

Following a detailed homoeopathic consultation with assessment of signs and symptoms, each patient was treated with individualized homoeopathic medicine after repertorization on CARA software in final consultation with material medical based on homoeopathic principle. Total fifty three (53) cases were prescribed with *Sepia officinalis*, single dose in 30C potency, 4 pills (size 30) on empty stomach. Medicine was repeated first in the same potency and subsequently in higher potencies as per the need of the case. Some of the important features of *Sepia* in relation to our study are given below.

Some of the characteristic indications of patients prescribed with *Sepia officinalis* are as follows:

- Indifference towards family, relatives
- Becomes angry on contradiction
- Changeable mood; Overanxious; Oversensitive, Weeps easily; Desires Company; Forgetfulness
- Irritability on consolation
- Becomes irritable when disturbed
- In general, aggravates in the morning
- Hot flushes worse from exertion; Hot flushes with perspiration
- Tendency to catch cold
- Aversion to milk; Desires sweets; Desires cold drinks; aggravation from fatty food
- General weakness, palpitation
- Diminished appetite
- Perspiration – scanty; Offensive perspiration
- Sour taste in the mouth
- Menses copious during menopause
- Leucorrhoea – thin; Leucorrhoea < morning
- Vaginal pain worse during coition
- Leucorrhoea white
- Burning pain in the soles; Dryness of the soles; Sensation of lump in the throat; Right sided headache; Sudden urging for urination; Paleness of skin

The data were analysed statistically by using the “Wilcoxon sign rank test” on SPSS software for the symptoms score and gynaecological findings and “t test” for laboratory findings. After completion of treatment for one year period, the outcome was assessed by using the following formula.

$$\% \text{improvement} = \frac{\text{Score at entry} - \text{Score at Completion}}{\text{Score at entry}} \times 100$$

Accordingly, improvement indices were formulated as marked improvement (75% or more improvement in symptoms score from baseline score), moderate improvement (50% to 75% improvements from baseline score), mild improvement (25% to <50% improvement from baseline score) and no significant improvement (<25% improvement from baseline score).

RESULTS

In the study period, 53 patients were prescribed with *Sepia officinalis* on the basis of totality of symptoms through repertorization and followed up for 1 year. The mean age of Sepia patients in this analysis was found to be 46.87 years (Table 1).

Table 1: Demographic and Baseline Data

Age profile	No (%)	Mean(SD)
40-50 years	44(83.0)	46.87(4.04)
50-60 years	9(17.0)	
Intensity		
Mild(4-11)	17(32.1)	8.6(1.5)
Moderate(12-24)	36(67.9)	16.0(2.9)
Severe(25-36)	0	0
Symptoms	No (%)	Median (IQR)
Hot Flushes	49(92.4)	1(1 to 2.5)
Night sweats	45(84.9)	1(1 to 2)
Anxiety	48(90.5)	1(1 to 2)
Depression	37(69.8)	1(1 to 1.5)
Palpitation	41(77.3)	1(1 to 1)
Pruritis vulvae	18(33.9)	0(0 to 1)
Dysuria	19(35.5)	0(0 to 1)
Sexual desire (change from previous)	30(56.6)	1(0 to 2)
Poor memory	44(83.0)	1(1 to 2)
Stress	28(52.8)	1(0 to 1)
Dyspareunia	11(20.7)	0(0 to 0)
Vaginal dryness	15(28.3)	0(0 to 1)
Discharge per vagina	28(52.8)	1(0 to 1)
Insomnia	31(58.4)	1(0 to 1)
Work & activities affected	46(86.7)	1(1to 2)
Total symptom score‡	53(100)	13.68(4.27)‡

‡Express in terms of Mean (SD)

The intensity of menopausal distress was assessed through baseline symptom score at entry as per the DDCYSS. Seventeen (17) participants having baseline score between 4 and 11 were classified as mild, 36 participants having a baseline score between 12 and 24 were classified as moderate. It was found that at completion, 2 patients were having moderate intensity of symptoms and 51 participants were having mild intensity of symptoms (patients with symptom score less than 4 at completion were also included in mild category). The DDCY Symptoms Score was used to assess the patient's condition from baseline up to 1 year (Table 2). The mean symptom score at the base line was 13.68(4.27) and at the end of treatment is 2.81

(2.63) and it was found to be statistical significant ($P < 0.05$)

Table 2: Comparison of symptoms in DDCYSS with Pre-Post analysis

Symptoms	Median(IQR)score		Z value	p value
	at entry	at end		
Hot Flushes	1(1 to 2.5)	0(0 to 0.5)	5.827	0.001*
Night sweats	1(1 to 2)	0(0 to 0)	5.641	0.001*
Anxiety	1(1 to 2)	0(0 to 0)	5.701	0.001*
Depression	1(1 to 1.5)	0(0 to 0)	5.209	0.001*
Palpitation	1(1 to 1)	0(0 to 0)	5.777	0.001*
Pruritis vulvae	0(0 to 1)	0(0 to 0)	3.499	0.001*
Dysuria	0(0 to 1)	0(0 to 0)	4.119	0.001*
Change in sexual desire	1(0 to 2)	0(0 to 0)	3.874	0.001*
Poor memory	1(1 to 2)	0(0 to 1)	4.746	0.001*
Stress	1(0 to 1)	0(0 to 0.5)	4.347	0.001*
Dyspareunia	0(0 to 0)	0(0 to 0)	2.714	0.007*
Vaginal dryness	0(0 to 1)	0(0 to 0)	3.638	0.001*
Discharge per vagina	1(0 to 1)	0(0 to 0)	4.625	0.001*
Insomnia	1(0 to 1)	0(0 to 0)	4.083	0.001*
Work & activities affected	1(1 to 2)	0(0 to 1)	5.896	0.001*
Total symptom score‡	13.68(4.27)	2.81(2.63)	21.62	0.001‡

* P value is significant at $p < 0.05$ by using Wilcoxon sign rank test

‡ P value is significant at $p < 0.05$ by using Paired t test

Out of 53 patients who completed their follow up, 37 patients showed marked improvement, 14 patients showed moderate improvement and 2 patients showed mild improvement. FSH reduced in 24 cases out of 40 cases that were investigated for FSH at the end of treatment. Out of 15 patients who were investigated for lipid profile on completion of the study, the level of lipid cholesterol and Triglycerides (TG) were reduced in 6 patients, HDL was increased in 12 patients which is statistically significant ($P = 0.024$), LDL was decreased in 8 cases and VLDL was decreased in 7 cases. Changes in FSH and lipid profiles are not statistically significant except HDL (Table 3). As regards gynecological findings, Cervicitis was found in 15 cases and got markedly improved in 13 cases, which is statistically significant ($P = 0.005$); Cervical erosion, Hypertrophied lip of cervix and Rectocele was found in 1 case each and got markedly improved. Candid discharge

per vaginum was found in 11 cases and got markedly improved in 7 cases. Trichomonas vaginalis discharge was present in 9 cases and got improved in 5 cases. Retroverted uterus was found in 21 cases, and became normal in 13 cases, which is statistically significant ($P=0.004$) (Table 4).

Tenderness on examination was present in 10 cases, and was improved in 9 cases after treatment, which is statistically significant ($P=0.011$). There was fluid in the pouch of Douglas in 5 cases which got cleared in 4 cases. (Table – 5).

Table 3: Statistical analysis of Laboratory Investigations at entry and at end

Parameters	Entry	End	Mean difference	95% CI	P value
	Mean(SD)	Mean(SD)			
Serum FSH	62.2(44.5)	73.1(52.8)	-10.8	-10.3 to 9.7	0.949
Lipid cholesterol	189.1(33.9)	193.4(22.1)	-4.3	-14.6 to 6.1	0.391
TG	141.3(48.8)	140.3(41.7)	1.0	-22.7 to 24.8	0.927
HDL	40.1(7.6)	47.9(7.1)	-7.9	-14.6 to -1.2	0.024*
LDL	119.4(29.7)	118.1(20.5)	1.4	-10.4 to 13.1	0.809
VDL	27.5(10.9)	28.1(8.3)	-0.5	-5.7 to 4.7	0.835

* Statistically significant at $p<0.05$

Table 4: Gynaecological findings

Symptoms	Median (IQR)		Z value	p value
	at entry	at end		
Condition of Cervix	1(1 to 2)	1(1 to 1)	2.8	0.005*
Nature of discharge	3(2 to 3)	3(2 to 3)	0.4	0.672
Position of uterus	2(1 to 2)	1(1 to 1.7)	2.8	0.004*
Tenderness	2(2 to 2)	2(2 to 2)	2.5	0.011*
pouch of douglas	3(3 to 3)	3(3 to 3)	1.3	0.18
Bleeding	2(2 to 2)	2(2 to 2)	1.4	0.157

* P value is significant at $p<0.05$ by using Wilcoxon signed rank test

Table 5: Gynaecological findings at baseline and at end of treatment

Gynaecological examination	P/V & P/S findings	Present at baseline (n)	Improved at completion (n)	Improved at completion (%)
Condition of Cervix	Cervicitis	15	13	86.66
	Cervical erosion	1	1	100
	Senile vaginitis	3	1	33.33
	Hypertrophied	1	1	100
Nature of discharge	Candid discharge	11	7	63.6
	TV discharge	9	5	55.5
Position of uterus	Retroverted	21	13	61.9
	Rectocele	1	1	100
	Cystocele	6	2	33.3
Tenderness	Present	10	9	90
Pouch of Douglas	Fluid	5	4	80
Bleeding	Present	5	2	40

DISCUSSION

In this analysis, it was observed that out of 53 patients, 37 patients showed marked improvements, 14 patients showed moderate improvement, and 2 cases showed mild improvement. *Sepia officinalis* is a very good medicine for Distress During Climacteric Years (DDCY), if prescribed on the totality of symptoms of patients. It was found that *Sepia* when selected on the basis of presenting symptoms

of menopause and characteristic attributes of the patient, improved the patients as a whole. On analyzing the additional data, it was found that cervicitis, cervical erosion, and rectocele were also improved. This is again a reconfirmation of the holistic tenet of Homoeopathy where a holistically selected similimum not only relieves the primary complaint of the patient but at the same time takes care of other problems as well. In the present day scenario with HRT scare, women are looking forward to safer and

effective options of treatment. This analysis reconfirms the scope of Sepia for effective management of menopausal complaints.

In a study by Bordet et al [7] it was observed that Sepia was the medicines found frequently indicated and useful along with other medicines. This corroborates with our present analysis. Sepia and other medicines have been successfully used by homoeopathic practitioners for the treatment of menopausal distress syndrome [8-10]. Our analysis also supports findings of these studies. Sepia along with other medicines is also mentioned as first-grade medicines under the rubric “menopause” in the Synthesis Repertory [11]. In a pilot study [12] on “homoeopathic treatment for hot flushes”, Sepia was found as one of the most effective medicine. In a prospective observational study [13] on the “Homoeopathic approach to the treatment of symptoms of estrogen withdrawal in breast cancer patients”, Sepia was found as the one of the most effective medicine. All above mentioned studies corroborate with our analysis.

As the homoeopathic system of medicine is based on individualization, it cannot be claimed beforehand that Sepia is the medicine for menopausal distress. If Sepia is indicated after repertorisation of the case and in final consultation with material medical then only Sepia can be prescribed. The another constraint was that follow up period of the cases was only for 1 year as per protocol [14], so no case could be labeled as ‘cured’. More period for the follow up of the study could have yielded better results as perimenopausal period is approximately 5-7 years.

CONCLUSION

The results of the analysis imply that Sepia prescribed on the basis of totality of symptoms act holistically in relieving symptoms of menopause. Further RCT are being conducted to validate the effectiveness of Sepia in DDCY.

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